INSTRUCTIONS FOR USE

SYNTHECON PDO

ABSORBABLE POLY(P-DIOXANONE) SUTURES

DESCRIPTION:
Synthecon PDO is a sterile, synthetic, absorbable, monofilament surgical suture composed of poly(p-dioxanone). The suture is available in both dyed (violet) and undyed (clear) forms to enhance visibility in the surgical field. Synthecon PDO sutures conform to the requirements specified in the European Pharmacopoeia and the United States Pharmacopeia.

INDICATIONS:
Synthecon PDO absorbable sutures are indicated for use in general soft tissue approximation and/or ligation where temporary wound support is required, including use in ophthalmic procedures. PDO sutures are not intended for use in cardiovascular or neurological tissues where prolonged tensile strength may be required.

ACTIONS:
Synthecon PDO absorbable sutures provide temporary wound support and elicit a minimal acute inflammatory tissue reaction, followed by gradual encapsulation by fibrous connective tissue. The sutures are gradually absorbed through hydrolysis, resulting in a gradual loss of tensile strength and eventual absorption of the suture material through breaking down biocompatible byproducts that are metabolized by the body. Sutures may not require mechanical removal.

TENSILE STRENGTH RETENTION:
Synthecon PDO retains approximately 95% of its tensile strength at 7 days post-implantation, 85% at 14 days, 80% at 21 days and 65% at 28 days, with absorption generally complete within 180–240 days.

CONTRAINDICATIONS:
This suture, being slowly absorbed, should be used where extended approximation of tissue is required.

WARNINGS:
Before employing Synthecon PDO absorbable sutures, users should be familiar with surgical techniques for absorbable sutures and proper wound closure procedures. Risk of wound dehiscence may occur depending on the surgical site. Extra caution is advised in elderly, malnourished, debilitated, or patients with delayed wound healing. Absorbable sutures may require additional support with non-absorbable sutures in areas subject to expansion, stretching, or distension. Do not re-sterilize or reuse. Reuse may compromise suture integrity and increase the risk of infection or transmission of blood-borne pathogens. Discard opened packages and unused sutures. Prolonged contact with salt-containing solutions (e.g., urine or bile) may result in calculus formation. Absorbable sutures may act transiently as a foreign body; follow accepted surgical practice for contaminated or infected wounds.

PRECAUTIONS:
Skin sutures left in place longer than one week may cause localized irritation; remove or snip as appropriate. Delayed absorption may occur in tissues with poor blood supply. Avoid crushing, crimping, or excessive handling of sutures with instruments. Ensure knot security using flat, square ties with additional throws as needed. Handle needles carefully: grasp 1/3 to 1/2 distance from the swaged end; do not reshape needles, as this may weaken them. Exercise caution to avoid needle sticks; discard used needles in approved “sharps” containers. Sutures are sterilized with ethylene oxide; do not use if the package is opened or damaged. Discard unused sutures from opened packages.

ADVERSE REACTIONS:
Adverse effects associated with the use of this device include wound dehiscence or inadequate wound support, particularly in areas subject to expansion, stretching, or distension, or in elderly, malnourished, debilitated, or patients with delayed wound healing. Localized irritation may occur if skin closures remain in place for longer than one week. Broken needles may lead to additional surgical procedures or residual foreign bodies.

STERILITY:
Synthecon PDO sutures are sterilized by ethylene oxide. Do not re-sterilize! Do not use if package is opened or damaged! Discard opened unused sutures.

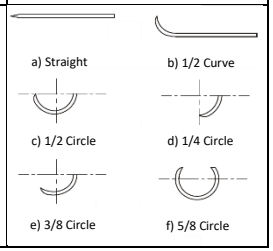
STORAGE:
Recommended storage condition below 25 ºC, away from moisture and direct heat. The shelf life of Synthecon PDO is five years. Do not use after expiry date.

SUPPLY:
Synthecon PDO detailed specification of suture length, needle profile, needle curvature read the primary label on the suture pack.

DEVICE READINESS:
Ready to use as found inside the container.

MANUFACTURING CONDITIONS:
Manufactured under an ISO 13485 Quality Management System to ensure these medical devices are safe, effective, and ready for clinical use with minimal risk and maximum patient benefit.

PRODUCT SPECIFICATIONS:

USP Sizes (mm)	Metric size (Gauge No.) Max.	Needle Profile	Needle curvature
2	5	TAPER POINT	
1	4	TAPER BLUNT	
0	3.5	REVERSE CUTTING	
2-0	3	STRAIGHT CUTTING	
3-0	2	SPATULA	
4-0	1.5	COLT	
5-0	1		
6-0	0.7		

DISPOSAL
To be disposed as per user’s country disposal regulations and hospital/clinic protocol.

EXPLANATION OF SYMBOLS:

Symbol	Explanation
	Manufacturer
	Manufactured date
	Use until
STERILE EO	Sterilization by Ethylene oxide
	Do not re- use
	Do not re-sterilize
LOT	Batch
	Keep from Sunlight
	Keep dry
	Warning
	Temperature limitation
	Don’t use when packing damaged

MANUFACTURED BY:


Synthecon

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1600, GAUTENG, SOUTH AFRICA

Synthecon

TECHNIQUE FOR OPENING THE TEAR OPEN PACK